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Original Article

# Effect of urethral meatus cleansing on midstream urine contamination rate in boys

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## Abstract

***Background*** Clean-catch midstream urine (MSU) remains the standard procedure for urine collection even if it's role to reduce bacterial contamination rate is unclear.

***Objective*** To compare bacterial contamination rate between clean-catch (cleaning urethral meatus with medicated soap) and non clean-catch MSU among boys.

***Methods*** An experimental study with parallel groups and block randomization was conducted. Toilet-trained boys aged 3 to 18 years, without symptoms or signs of urinary tract infection were recruited from the Pediatric Outpatient Clinic at Sardjito Hospital and from a local elementary school. Subjects with history of renal disease, those who were on under antibiotic treatment in the preceding week, or with meatal abnormality or non-cooperative were excluded. Urine specimen was collected by a trained nurse, and was cultured within one hour by personnel blinded to the assignment. Significant bacteriuria was defined as growth of a single pathogenic organism (degree of pathogenicity group I-III) with colony count ≥105 colony forming unit/ml. Contamination was defined as any growth not fulfilling criteria for significant bacteriuria or growth of multiple organisms.

***Results*** A total of 80 boys were enrolled. The contamination rate in the clean-catch group was 13% (5 out of 40) compared with 10% (4 out of 40) in the non clean-catch group (P=1.0). The adjusted risk ratio for contamination in the clean-catch MSU group, adjusted to age and circumcision status, was 1.37 (95% CI 0.42; 4.51).

***Conclusion*** Clean-catch method does not reduce bacterial contamination rate of midstream urine cultures in boys **[Paediatr Indones 2008;48:180-5]**.

***Keywords****: clean-catch, non clean-catch, midstream urine, contamination rate*

Urinary tract infection (UTI) is common among young children, with 3.3% (95% CI 2.6; 4.0) overall prevalence among febrile children less than two years old.[1] The recurrence rate of UTI is high and has positive correlation with long-term sequelae such as hypertension and renal insufficiency. Accurate diagnosis is essential for early management and prevention of long-term sequelae.[2-4] The gold standard for UTI diagnosis is positive culture from a properly collected urine specimen.[5] Interpretation of urine culture results based on inappropriately collected urine specimen can lead to underdiagnosis or overdiagnosis, and further unnecessary treatment, hospitalization and diagnostic imaging procedure with the risk of complications and psychological stress for patient and family.[4,6,7]

Since 1958, clinicians have favoured midstream urine (MSU) collection, which is non-invasive, not causing iatrogenic UTI, and can be easily collected from a child with bladder control.[8,9] The standard method is clean-catch MSU, which refers to perineal

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and meatal cleansing before urine collection to reduce specimen contamination by perineal flora.[9-12] A recent randomized trial among children found significantly lower contamination rates in clean-catch MSU.[4] Although other researches among adults and children failed to demonstrate the benefit of clean-catch MSU, this method remains the standard for urine collection in the past 50 years[9-18] including the guideline by National Institute for Health and Clinical Excellence (NICE) in 2007. Nowadays, there is no universally accepted protocol for clean-catch MSU. Most protocols vary considerably in the practice, the techniques and equipment used in the cleaning process.[18]

The objective of this study was to compare bacterial contamination rate between clean-catch MSU and non clean-catch MSU among boys.

## Methods

An experimental study with parallel groups and block randomization was conducted among toilet-trained boys aged 3 to 18 years. Participants were recruited from the Paediatric Outpatient Clinic at Sardjito Hospital and from a local elementary school. Subjects without symptoms or signs of urinary tract infection were recruited. Written informed consent was obtained from the parents or guardian before enrollment. Subjects with a history of renal disease, or under antibiotic treatment in the preceding week, or had meatal abnormality, or non-cooperative were excluded.

Enrolled children were randomized into two groups: clean-catch MSU group and non clean-catch group. A block randomization with a block size of eight was generated using computer and was used to assign equal numbers of children to each study group.

For initial screening, a history of renal disease and antibiotic treatment in the preceding week was assesed, then physical examination was done by a doctor to exclude meatal abnormality. Interview was done to obtain demographic data and circumcision status. Urine collection was done by a trained nurse. Before the procedure, the nurse washed his hands carefully with soap and water. For all uncircumcised boys, foreskin was retracted and maintained during urine collection. For clean-catch MSU group, the meatus and the tip of the penis was cleansed using cotton ball soaked with medicated soap containing 0,2% triclosan from the meatus outward with a circular motion. The cleansed area was rinsed using three water soaked cotton balls one at a time and then dried with sterile gauze. Subjects were asked to pass the first portion of urine into the toilet, the mid-portion into a sterile container and the rest into the toilet.

Urine specimens were sent immediately to the Clinical Pathology Laboratory at Dr. Sardjito Hospital. Specimens obtained from elementary school were transported with an ice-pack. Standard quantitative culture was performed within one hour after urine collection. A wire loop containing 10 $\mu$l of urine was used to inoculate CLED and MacConkey agar. All plates were incubated at 37$^{o}$C and bacterial growth was examined daily for two consecutive days. All laboratory personnel were blinded to the urine collection method.

Significant bacteriuria was defined as growth of a single pathogenic organism (degree of pathogenicity group I-III according to European Confederation of Laboratory Medicine's guideline) with colony count $\geq$105 CFU/ml. Asymptomatic bacteriuria was defined as significant bacteriuria of the same pathogen in two consecutive MSU cultures from an individual without symptoms or signs of UTI.[19] Contamination was defined as any growth not fulfilling criteria for significant bacteriuria or growth of multiple organisms. If significant bacteriuria developed, a careful history, physical examination, urine dipstick test and urine culture was repeated to reveal a UTI.

Based on the predicted contamination rate of 8% in the clean-catch MSU, significant level 0.05 and power 80%, the estimated number of children needed to detect a clinically important difference in contamination rates of 25% between groups was 40 in each group. Data were analyzed using Student's-t test for continuous variable and the chi-square (X2) statistic or Fisher's exact test for proportion. Risk ratio (RR) and its 95% CI for contamination in the clean-catch MSU group were calculated. The modified Poisson regression was used to adjust for potential confounders such as age and circumcision status. This study was approved by the Ethics Review Committee of Gadjah Mada University.

## Results

At the beginning of the study, four children were excluded: three children were not cooperative and one had phimosis. After randomization, 7 children failed from the clean-catch MSU group (one child was not cooperative, 6 children could not urinate) and 2 children from the non clean-catch group (one child was not cooperative and the other had inadequate urine volume). Subject recruitment continued until 80 children were enrolled, with 40 children in each group.

Fifty-five children were recruited from elementary school and the rest 25 were recruited from the outpatient clinic. There was no significant difference of mean age between children enrolled from elementary school and from the outpatient clinic. Forty-nine of 80 children were uncircumcised. Baseline characteristics of the subjects were comparable between clean-catch MSU and non clean-catch MSU group (**Table 1**).

Out of 80 specimens, 71 (89%) were sterile, 2 (3%) were classified as significant bacteriuria and 7 (9%) were contaminated. The description of children with bacteriuria (significant or contaminated) is depicted in **Table 2**.

As defined, bacterial growth in all contaminated specimens were <105 CFU/ml as seen in **Table 1**. Statistical analysis yielded no significant difference in colony count between the clean catch and non-clean catch group (P=0.55; Fisher's exact test).

In this study, specimens with significant bacteriuria and the contaminated cultures grew only 1 pathogenic organism. The two with significant bacteriuria grew secondary pathogens (S. faecalis and P. aeruginosa) while from contaminated specimens, 5 grew secondary pathogens (P. aeruginosa (n=2); K. pneumonia (n=3)) and 2 were primary pathogens (S. saprophyticus). So seven of nine isolated pathogens were secondary pathogens and two were primary pathogens. No significant difference was found between clean-catch and non clean-catch MSU group (P=1.0; Fisher's exact test).

Following careful history and physical examination, the 2 children with significant bacteriuria were confirmed to have no symptoms or signs of UTI. Urine dipsticks were negative for leukocyte esterase and nitrites. Repeated clean-catch urine cultures 1-2

**Table 1.** Baseline characteristics of study subjects

| Characteristic | Clean-catch MSU (n=40) | Non clean-catch MSU (n=40) |
|---|---|---|
| Age, mean (SD), mo | 106.6 (25.2) | 115.6 (25.1) |
| Source of subjects, n | | |
| Outpatient clinic | 11 | 14 |
| Elementary school | 29 | 26 |
| Circumcision status, n | | |
| Circumcised | 17 | 14 |
| Uncircumcised | 23 | 26 |

* t-test; † Chi-square test

**Table 2**. Subjects with significant bacteriuria and contaminated culture (European Confederation of Laboratory Medicine's guideline)

| Circumcision status | Urine collection method | Colony count (CFU/ml) | Types of pathogen |
|---|---|---|---|
| Significant bacteriuria | | | |
| Uncircumcised | Clean-catch | 105 | S. faecalis |
| Uncircumcised | Clean-catch | 105 | P. aeruginosa |
| Contamination | | | |
| Uncircumcised | Non clean-catch | 7 x 104 | S. saprophyticus |
| Circumcised | Non clean-catch | 4 x 104 | P. aeruginosa |
| Uncircumcised | Non clean-catch | 3.5 x 104 | P. aeruginosa |
| Uncircumcised | Non clean-catch | 2.8 x 104 | K. pneumonia |
| Uncircumcised | Clean-catch | 2.5 x 104 | K. pneumonia |
| Circumcised | Clean-catch | 1.4 x 104 | K. pneumonia |
| Uncircumcised | Clean-catch | 1.1 x 104 | S. saprophyticus |

weeks after the first cultures were also sterile. There were no history of antibiotic treatment in between. Since repeated urine cultures didn't confirm asymptomatic bacteriuria, both were later considered as contamination.

The contamination rate was 13% (5 out of 40) in the clean-catch MSU group compared to 10% (4 out of 40) in the non clean-catch MSU group, which was not significantly different (P=1.0; Fisher's exact test)

The modified Poisson regression analysis confirmed that circumcision status and age were not confounders in this study and did not affect the contamination rates (adjusted risk ratio 0.41 [95%CI 0.12; 1.36] and 1.0 [95%CI 0.96; 1.05] respectively). The adjusted risk ratio for contamination in the clean-catch MSU was 1.37 (95%CI 0.42; 4.51).

**Table 3.** Adjustment of contamination risk for potential confounder

| Variable | Contamination risk | |
|---|---|---|
| | Unadjusted Risk Ratio (95%CI) | Adjusted Risk Ratio (95%CI)* |
| Urine collection method | | |
| Clean-catch MSU | 1.25(0.36; 4.32) | 1.37(0.42; 4.51) |
| Non clean-catch MSU | 1.00 | 1.00 |
| Circumcision status | | |
| Circumcised | 0.45(0.10; 2.04) | 0.41(0.12; 1.36) |
| Uncircumcised | 1.00 | 1.00 |
| Age (months) | - | 1.00(0.96; 1.05) |

* Modified Poisson regression (adjusted for circumcision status and age)

## Discussion

Various studies reported substantial different contamination rates in clean-catch MSU and non clean-catch MSU specimens because of the different criteria for urine contamination. Two previous studies in children used the criteria of a single organism <104 CFU/ml growth or growth of two or more organisms to define contaminated culture.[9,16] The European Confederation of Laboratory Medicine (ECLM) guideline,[20] which is based on colony count, urine collection method, patient's sex, presence or absent of UTI symptoms and degree of pathogenicity of isolate, was used for urine culture interpretation in our study.

We noted that the contamination rate was higher in the clean-catch MSU group compared to non clean-catch group (13% vs. 10%), but the difference was not statistically significant (RR 1.25, 95%CI 0.36; 4.32). Previous studies among children and women also found non-significant higher contamination rate in the clean-catch MSU (10% vs. 5% and 31.5% vs. 28.6%, respectively).[9,15] Possible causes were contamination from the equipment, materials or contamination during the cleansing process. This was supported by the evidence that 67% of the isolated pathogens in this study was gram negative bacteria, such as P. aeruginosa and K. pneumoniae which are frequently found in hospital.

Kampf and Kramer[21] found high contamination rate of nosocomial pathogens on health care worker's hands and inanimate objects which persist for a long time. The contamination rate of Pseudomonas spp. on hands was 1.3-25%, and it persisted for 30 to 180 minutes and on inanimate objects for 6 hours to 16 months. Klebsiella spp. was found on 17% of health care worker's hands and persisted for 120 mins and on inanimate objects for 2 hours to 30 months. Persistence of nosocomial pathogens on inanimate objects is of particular concern, due to hands contamination following contact with the objects.

Contamination can also occur during the cleansing process with soap and water, e.i contamination of P. aeruginosa. Plain soap may be contaminated which leads to colonization of Serratia marcescens or S. liquefaciens on health worker's hands or nosocomial infection. Kampf *et al*[21] reported contamination of antiseptic hand washing solution containing 1% triclosan by S. marcescens in operating theatres and ICU.

The efficacy of medicated soap to reduce bacterial count depends on the concentration of active substance and the duration of cleansing process. Microbiology studies showed the usual triclosan concentrations in medicated soap (0.2-0.3%) did not achieve higher efficacy compared with plain soap

(Aiello *et al*[23]). Significant difference was observed after longer duration of cleansing with higher triclosan concentrations (≥1%). Most studies evaluated medicated soap efficacy after ≥30 seconds cleansing period. Longer duration of cleansing process will give better efficacy.[22]

The low concentration of triclosan in the medicated soap used in this study, i.e. 0.2% and the short duration of the cleansing process may also contribute to the insignificant results. Prolonging meatal cleansing is not feasible as it may irritate the meatus and more uncomfortable for the children.

In similar studies, meatal cleansing and urine collection were performed by parents or children after explanation, with or without supervision from the nurse. [4,9,16] In our study, these were done by a trained nurse to ensure that the results were not caused by improper technique. On the other hand, contamination of urine specimens by antiseptic solution used for the cleansing process may also reduce colony count, leading to false negative results.[18]

Clean-catch MSU method is not practical, time and resources-consuming and often not performed properly despite adequate instructions.[4,7,11,15,18] It also cause embarrassment both in the patients and nurses during introduction of the procedure.[15] Urethral meatus and periurethra of uncircumcised boys potentially have higher concentration of uropathogens compared with circumcised boys.[5,24] This study found no significant effect of circumcision on the contamination rate of MSU cultures. Lipsky *et al*[13] also reported that circumcision status and urine collection methods did not affect contamination rate. The first portion of urine can wash off contaminants in the urethra with MSU collection.[25]

The only report of significant difference between clean-catch vs non clean-catch MSU was by Vaillancourt *et al*.[4] In this randomized trial, culture was done in children with positive urinalysis results (positive leukocyte esterase and/or nitrites on dipstick or ≥5 leukocytes/high powered field microscope). But there was an imbalance of subjects (37 clean-catch vs 63 non clean-catch ).

This study was designed to detect a 25% contamination rate between clean-catch MSU and non clean- catch MSU which is clinically important. But it is shown that the study could not detect the small but significant difference. Our data confirm the existing evidence that clean-catch method does not reduce bacterial contamination rate of midstream urine culture in boys.

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